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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,096	03/19/2004	Pierre Marraccini	88265-6868	7981
28765	7590	01/28/2005	EXAMINER	
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			KOROMA, BARBA M	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/804,096

**Applicant(s)**

MARRACCINI ET AL.

**Examiner**

Barba M. Koroma

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/19/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group I, claims 1-7, 12-14, in the paper filed November 29, 2004, is hereby acknowledged.

### ***Response to Traversal of Restriction Requirement***

2. This is not found persuasive because the claims of group I are drawn to a product, a coffee plant, and the claims of group II are drawn to a method. A method of increasing solubility of coffee can be practiced using other and materially different products. Furthermore, a search directed at a method for increasing solubility without extending the search into multiple and various other classes and subclasses of inventions, may not necessarily yield information on the coffee cells of Group I. Further, the coffee cells and plants of Group I can be used in other methods, such as in crosses with other coffee plants to produce new varieties. Claims 1-7 and 12-14 have been examined in this Office action. The restriction of Groups I and II are deemed proper and hereby made FINAL. Non-elected claims 8-11 are withdrawn from consideration. (See below).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the

allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re: Ochiai, In re: Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

See MPEP § 804.01.

***Claim to Priority date***

3. Applicant is required to submit a certified copy of the PCT priority document, PCT/EP02/09148.

***Objections to specification***

4. The phrase “in the over hand” (page 9, second paragraph, line 1) should read “--in the other hand--”. Correction is requested.

It is suggested that the entire specification be reviewed and corrected for similar typographical errors.

***Claim Rejections – 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to teach a transformed plant with reduced galactosidase activity, increased galactose branching, and increased solubility of coffee.

The claims are broadly drawn to a coffee plant that produces galacto-mannans modified to reduce endogenous levels of  $\alpha$ -D-galactosidase activity in order to increase galactose branching of the galacto-mannans; the coffee plant cell containing a nucleic acid transcribed to a ribonucleic acid which is anti-sense to mRNA, the full length coding sequence, or a part thereof, under the control of a coffee *cspI* promoter, derived from  $\alpha$ -D-galactosidase gene of a coffee cell capable of forming dimers under physiological conditions; a coffee plant cell and beans, obtainable from the coffee plant.

The specification teaches that  $\alpha$ -D-galactosidase full-length cDNA sequence was isolated from a cDNA library of coffee plant 30 weeks after flowering (page 5, lines 30-33), cloned into the pCR script Amp SK (+) vector to give the pLP1, (second paragraph, page 6, example II). The specification indicate that anti-sense gene construct or cassette of coffee  $\alpha$ -D-galactosidase cDNA placed under the control of the *cspI* 11S-coffee promoter an expression cassette was constructed (example IV, pages 7-8; page 9, lines 18-20), cloned in the anti-sense direction, and then used to transform *A. tumefaciens*. Wounded somatic embryos of coffee plant leaf explants

were finally transformed by co-culturing with antisense DNA-carrying recombinant *A. tumefaciens* ((page 10, lines 12-14; page 11, lines 2-3). To check the effectiveness of the transformation, several individual plants were selected and propagated *in vitro* by micro cuttings (page 11, lines 16-18). The specification indicates that antisense galactosidase-transformed somatic embryos were analyzed by RT-PCR (section VIII, pages 11-12).

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: *Lack of guidance*; The specification does not teach  $\alpha$ -D-galactosidase antisense-transformed plant(s) that exhibit reduced  $\alpha$ -D-galactosidase activity, increased galactose branching, and increased solubility of coffee. *State of the prior art*: the prior art does not teach the part(s) or regions of the cDNA of the 1263bp  $\alpha$ -D-galactosidase gene that is critical for its inhibition when expressed in anti-sense orientation. *The unpredictability of the art*; anti-sense oligonucleotide constructs are not guaranteed to work. For example, Shen et al (2001. *European J. Biochem.* p2331-2337) showed that anti-sense oligonucleotide constructs designed to target three different regions of TGF- $\beta$ 2 mRNA differentially inhibit the target gene, with the anti-sense construct targeted to the translation initiation site demonstrating the most selective inhibitory effect of TGF- $\beta$ 2 production in osteoblast cells. This demonstrates that random fragments of a coding sequence cannot be predicted to direct antisense-mediated suppression of the coding sequence; *Quantity of experimentation necessary*: Because the specification does not teach a plant that has reduced  $\alpha$ -

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D-galactosidase activity, increased galactose branching, and increased solubility of coffee, achieved by antisense oligonucleotide-transformation method, it will require undue experimentation to evaluate thousands of cDNA fragments to determine how the full-length cDNA of  $\alpha$ -D-galactosidase might be truncated or reduced to yield a part(s) that can effectively inhibit endogenous  $\alpha$ -D-galactosidase activity. See In Re: Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), it is taught that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. Given the scope of the claims broadly drawn to a coffee plant that produces galactomannans modified to reduce endogenous levels of  $\alpha$ -D-galactosidase activity in order to increase galactose-branching of the galacto-mannans, and increase solubility of the coffee, and the lack of guidance of the specification, it would require undue experimentation by one skilled in the art to make and use the invention, as claimed.

6. Claims 1-7, and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for modification of the coffee plant cell so as to reduce  $\alpha$ -D-galactosidase activity using antisense oligonucleotides, thereby producing increased galactose branching of galacto-mannans, and increased water solubility.



The claims are broadly drawn to a coffee plant that produces galacto-mannans modified in any way to reduce endogenous levels of  $\alpha$ -D-galactosidase activity in order to increase galactose branching of the galacto-mannans; the coffee plant cell possibly containing a nucleic acid transcribed to a ribonucleic acid which is anti-sense to mRNA, or a part thereof, or the coffee plant containing other modifying sequences such as ribozyme-encoding genes, modifier genes, etc, under the control of a coffee *csp1* promoter, derived from  $\alpha$ -D-galactosidase gene of a coffee cell capable of forming dimers under physiological conditions; a coffee plant cell and beans, obtainable from the coffee plant.

The specification teaches that  $\alpha$ -D-galactosidase full-length cDNA sequence was isolated from a cDNA library of coffee plant mRNA 30 weeks after flowering (page 5, lines 30-33), cloned into the pCR script Amp SK (+) vector to give the pLP1, (second paragraph, page 6, example II). Results from Northern blotting of galactosidase-containing plants showed a peak of galactosidase gene expression in early phase endosperm development (3<sup>rd</sup> paragraph, page 7). Alpha-D-galactosidase anti-sense gene construct or cassette of coffee  $\alpha$ -D-galactosidase cDNA placed under the control of the *csp1* 11S-coffee promoter an expression cassette was constructed (example IV, pages 7-8; page 9, lines 18-20), and subsequently used to transform coffee cell suspension (page 9, lines 21-22). The same cassette is cloned in the anti-sense direction (page 10, lines 12-14) and then used to transform *A. tumefaciens*. Wounded somatic embryos of coffee plant leaf explants were finally transformed by co-culturing with antisense DNA-carrying recombinant *A. tumefaciens* (lines 2-3, page 11). To check the effectiveness of the transformation, several individual plants were selected and propagated in vitro by micro cuttings

(page 11, lines 16-18), followed by RT-PCR analysis of antisense-transformed plants (section VIII, pages 11-12).

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are:

*Lack of guidance*; The specification does not teach that the coffee plants were actually modified by the process as claimed. Furthermore, the specification doesn't enable any other coffee plant modification process which involves reduction of galactosidase activity, increase galactose branching, and increased solubility of coffee. For example, the specification does not teach anything about how to regulate  $\alpha$ -D-galactosidase, nor does it teach for example regulatory proteins that control the expression of  $\alpha$ -D-galactosidase. *State of the prior art*: the prior art does not teach the part(s) or regions of the gene critical for inhibition of its activity. Thus, it is not known whether antisense inhibition would effectively reduce  $\alpha$ -D-galactosidase activity thereby resulting in increased galactose branching of galacto-mannans, and increased water solubility. This lack of crucial teaching makes it uncertain to what extent and in what tissues the purported modification of reduced galactosidase activity, increased galactose branching, and increased water solubility might occur; *Unpredictability of the art*: Shen et al (2001. *European J. Biochem.* p2331-2337) showed that anti-sense oligonucleotide constructs differentially inhibit a target gene, depending on what regions are targeted by the anti-sense inhibition. In other words, antisense constructs are not guaranteed to produce the intended results of effectively

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inhibiting a gene. Furthermore, even if antisense suppression of gene expression did occur, it is unpredictable whether said suppression would alter galactomannan branching. Willmitzer et al (1993. Plant Polymeric Carbohydrates. 33-39) teach that successful inhibition of branching enzyme did not result in any change in amount of branching of another carbohydrate, namely starch (see p37, bottom paragraph); p38, 3<sup>rd</sup> full paragraph). In addition, other non-exemplified types of modification of gene expression are unpredictable. For example, Kull et al (1995. J. Genet. & Breed. 49(1). p69-76) teach that ribozyme-encoding sequences designed to inhibit a starch metabolism gene had no effect on actual branching of that carbohydrate (see p69, abstract). *Quantity of experimentation necessary:* Because of the lack of teaching of a modification (reduction) of  $\alpha$ -D-galactosidase activity in transformed coffee plant tissues either by antisense RNA or any other non-exemplified means resulting in increased galactose branching of the galactomannans, and increased water solubility of antisense-transformed plants, it would require undue experimentation by one skilled in the art to make and use the invention, as claimed. See In Re: Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), it is taught that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-5 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as follows:

- a). Claim 2: The recitation “containing a nucleic acid” is indefinite. The recitation does not make clear whether the said nucleic acid is derived from another coffee plant, i.e. transferred by means of genetic recombination, or occurs naturally in the plant, i.e. endogenous. This rejection can be overcome by modifying the preamble to this claim as follows: insert --exogenous-- in line 2, before “nucleic”.
- b). Claim 12 recites “the coffee beans.” The claim from which claim 12 depends recites “coffee beans obtainable from the coffee plant”. It is unclear whether the coffee beans are obtained from the coffee plant which bears the properties of reduced  $\alpha$ -D-galactosidase activity, or from other coffee plants which do not.” It is suggested that the claim be amended to indicate that “obtainable” be replaced with --obtained--.

### ***Claim Rejections 35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhu and Goldstein (1994. Gene. vol. 140(2). p227-231).

Claim 7 is broadly drawn to coffee beans obtainable from the coffee plant of claim 6. The term "obtainable" indicates that the beans can be from any other coffee plant. Zhu and Goldstein teach the use of coffee beans from a coffee plant used as a source for isolating mRNA.

***Contact Information***

9. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.  
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